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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,955	11/16/2001	Mitradev Boolell	PCS10382ARTB	2910

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,955	BOOLELL, MITRADEV	
	Examiner	Art Unit	
	Brian S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9 and 10* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary of Action

I. The amendments filed August 14, 2003 and May 03, 2004 are objected to under 35 USC 132 because it introduces new matter into the disclosure.

II. Claims 1-7 and 9-10 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

III. The rejection of claims 1-7 and 9-10 under 35 USC 102(e) as being anticipated by Wilson et al. (US 6403597 B1) will not be maintained in light of the amendment.

IV. Claims 1-7 and 9-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Doherty et al. (US 6037346 A) and Wilson et al. (US 6403597 B1), and if necessary further in view of Bell-Huff et al. (EP 0960621 A2) and Ellis (WO 94/28902).

Status of Application

1. Receipt is acknowledged of applicant's filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.114.

Response to Amendment

2. The amendment filed August 14, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "without co-administration of an estrogen agonist/antagonist".

Applicant is required to cancel the new matter in the reply to this Office Action.

3. The amendment filed May 03, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "but not including buccally or sublingually".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-7 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims in this application introduce two negative limitations as discussed in preceding comments, namely "without co-administration of an estrogen agonist/antagonist" and "but not including buccally or sublingually". The examiner determines that when all evidences in the original disclosure are considered and carefully reviewed, the newly amended claims fail to find support in the original specification.

The specification discloses that as an embodiment of the invention, the PDE5 inhibitors can be combined with one or more additional active agents for the treatment of PD in patients

with normal erectile function (page 16, lines 14-16). Furthermore, the specification provides examples of various suitable agents for the claimed invention including estrogen agonist/antagonist (page 16, line 14 thru page 19, line 15). Specifically in page 17, lines 25-29, raloxifene or lasofoxifen and (-)-cis-6-phenyl-5-{4-(2-pyrrolidin-1-yl-ethoxy)-phenyl}-5,6,7,8-tetrahydronaphthalene-2-ol are disclosed as preferred estrogen agonists and/or estrogen antagonists. In addition, the specification discloses that the PDE5 inhibitors can be administered orally, buccally or sublingually in the tablets, capsules, multi-partculates, gels films, ovules, elixirs, solutions or suspension, which contain flavoring or coloring agents, for immediate-, delayed-, modified-, sustained-, pulsed- or controlled- release applications; and the PDE5 inhibitors may also administered as fast-dispersing or fast-dissolving dosage forms or in the form or a high energy dispersion or as coated particles (page 11, lines 9-15).

Therefore, it would have been clear to one skilled in the art, reading the instant disclosure, that the claimed invention can be practiced with (i) the PDE5 inhibitor in combination with other active agents disclosed in the specification including estrogen agonist/antagonist, not excluding estrogen agonist/antagonist as newly amended claims, and (ii) buccal or sublingual administration, not excluding buccally or sublingually.

As stated above, the specification only positively states about the boundaries of the claim. There is no express statement about the negative limitation that can be found in the specification. Thus, the exclusion of said elements implies the inclusion of all other elements not expressly excluded, clearly illustrating that such negative limitations do, in fact, introduce new matter. The negative limitation recited in the present claims, which did not appear in the specification filed,

introduces new concepts and violate the description requirement of the first paragraph of 35 USC 112.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-7 and 9-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Doherty et al. (US 6037346 A) and Wilson et al. (US 6403597 B1), and if necessary further in view of Bell-Huff et al. (EP 0960621 A2) and Ellis (WO 94/28902).

Doherty teaches the use of type V phosphodiesterase inhibitor (e.g., sildenafil, pyrazolopyrimidinone, zaprinast) for treating erectile dysfunction including premature ejaculation via local administration (abstract; column 5, lines 42-53; column 7, lines 11-15; claims), wherein said PED5 inhibitor is given a daily in the rage of approximately 0.1 to

500mg/day. Doherty also teaches that oral and parenteral administration of phosphodiesterase inhibitors are known for the treatment of erectile dysfunction (column 3, lines 7-11).

Wilson teaches the use of type V phosphodiesterase inhibitor (e.g., sildenafil, pyrazolopyrimidinone, zaprinast) for treating erectile dysfunction including premature ejaculation via transmucosal (i.e., buccal or sublingual) or local administration, wherein said PED5 inhibitor is given a daily in the rage of approximately 0.1 to 500mg/day.

Bell-Huff and Ellis teaches an oral, parenteral or sublingual or buccal administration of phosphodiesterase inhibitors such as sildenafil (5-[2-ethoxy-5-(4-methylpiperazin-1-ylsulphonyl)-phenyl]-1,6-dihydro-1-methyl-3-propylpyrazolo[4,3-d]pyrimidin-7-one).

The teaching of Doherty differs from the claimed invention in the use of PDE 5 inhibitor in "normal erectile function" and in oral form.

Although the reference is silent about the efficacy of PDE5 inhibitor in the treatment of premature ejaculation with "normal erectile function" patient, one having ordinary skill in the art would have motivated to apply the claimed PDE5 inhibitor (e.g., sildenafil), with reasonable expectation of success, to treat patients with premature ejaculation regardless of normal erectile function or erectile dysfunction. One having ordinary skill in the art would have known that PDE5 inhibitor would be effective in treating premature ejaculation in patients with "normal erectile function" as well as erectile problem patient. The state of the premature ejaculation treatment art does not distinguish between patient with "normal erectile function and patient with erectile function problem. Rather, the prior art generally teaches that any effective agents for the treatment of premature ejaculation would be effective in treating premature ejaculation regardless of "normal erectile function" or erectile problem. Based on the

state of the prior art, differences in "normal erectile function" will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such "normal erectile function" is critical.

In addition, those of ordinary skill in the art would have been readily optimized effective dosage form as determined by good medical practice and the clinical condition of the individual patient. Determination of the appropriate dosage form for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of known dosage forms of PDE5 inhibitor such as sildenafil citrate. Thus, one having ordinary skill in the art would have been motivated to make such modification to extend the usage of said PDE5 inhibitor by making the formulation in oral form to accommodate patient's preference and needs where the compliance could be greatly improved.

It is noted applicant that Wilson, Bell-Huff and Ellis references are being supplied as references to demonstrate known dosage formulations of PDE5 inhibitors (i.e., oral, buccal or sublingual, intravenous, topical, etc...) in the state of art.

Response to Arguments

6. Applicant's arguments filed May 03, 2004 have been fully considered but they are not persuasive.

In response to the rejection of the claims under 35 USC 112, first paragraph, as failing to comply with the written description requirement, applicant alleges that the specification clearly contemplates the use of PDE5 inhibitors without such agents ("the PDE5 inhibitors may also be

combined with one or more additional active agents for treating PD"). Applicant alleges that the use of the term may with reference to the use of combination agents clearly indicates that one embodiment of the invention is that the PDE5 inhibitors may be used without one or more additional agents.

The examiner disagrees with applicant's argument, and maintains that the negative claim limitations lack description in the specification. It appears that the applicant in this instant application attempts to avoid a prior art reference by excluding "co-administration of an estrogen agonist/antagonist" and "buccally or sublingually" administration. However, there is no distinguishable (patentable) reason to exclude "co-administration of an estrogen agonist/antagonist" and "buccally or sublingually" administration from the disclosed examples of various suitable agents and the disclosed mode of administrations. Furthermore, the exclusion of said element implies the inclusion of all other elements not expressly excluded, clearly illustrating that such negative limitations do, in fact, introduces new matter.

Conclusion

7. Amendment to the claims to remove new matter as set forth in this Office Action, absent other amendatory language, may necessitate reinstatement of previously made rejection(s) over prior art under 35 USC 102 and/or 35 USC 103.

8. No Claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614

VICKIE KIM
PRIMARY EXAMINER